

K023737

JUL 14 2003

SECTION 10 510(k) Summary Injector



diamond technology
Anton Meyer & Co. Ltd.
Helmstrasse 1
CH- 2560 Nidau
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510 (k) Summary “Injector”

October, 30th 2002

Submitted by:

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Director Marketing and Sales
Anton Meyer & Co. Ltd.
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Common Name: Injector

Classification Name: Intraocular lens guide, CFR 886.4300

1. Predicate Device:

The predicate devices to which we are claiming equivalence are:

- a) Hand piece of Micra Instrument Ltd. Lens Insertion System K 011392
- b) Hand piece of MONARCH® II IOL; K 003768
- c) Hand piece of Micro STAAR™ Injector; K983129
- d) Hand piece of AMO Phacophlex II; K961242

2. Device Description

The injector is an autoclavable, reusable titanium hand piece which is used to deliver folded intraocular lenses into the eye for replacement of the human crystalline lens.

3. Intended Use

The Royale® AE 9045 injector is intended as a reusable instrument to assist in implanting Alcon ACRYSOF® foldable intraocular lenses during a normal small incision cataract surgery. It is designed to incorporate Alcon cartridges Type C for foldable intraocular lenses. The cartridge is loaded into the injector body and by pushing the piston. The lens will be removed out of the cartridge and delivered to the desired position.

4. Summary of the Technological Characteristics of the Device

The injector reusable hand piece accepts the cartridges with a sterile single use cartridge which incorporates the folded lens and delivers the lens by using a plunger to express the lens. The plunger's head is contoured to provide a good contact to the lens as well as an adequate clearance for the trailing haptic. The plunger is advanced by direct forward motion applied to the syringe type plunger. Due to the ball bearing technology a smooth and well controlled lens delivery is ensured.

5. Summary of the Performance Characteristics

The performance tests for the injector will show that it can be used to deliver IOL cartridges (Type C Cartridges with the corresponding ACYSOF[®] Lens Models) without adversely affecting the overall power, shape resolution or cosmetic attributes of the lenses.

6. Summary of the Performance Data

The results of the non clinical performance testing will be subject to particular passing criteria that will support claim of substantial equivalence.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Anton Meyer & Co., Ltd.
c/o Thomas Meyer
Director, Marketing and Sales
Helmstrasse 1
CH-2560 NIDAU
Switzerland

Re: K023737
Trade/Device Name: Injector, Royale® AE9045
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I
Product Code: MSS
Dated: May 09, 2003
Received: May 14, 2003

Dear Mr. Thomas Meyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Thomas Meyer

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, reading "A. Ralph Rosenthal". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

A. Ralph Rosenthal, M.D.

Director

Division of Ophthalmic and Ear,

Nose and Throat Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

SECTION 2 Statement of Indication for Use

510(k) Number (if known): K023737

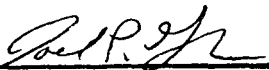
Device Name: Injector

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devices
510(k) Number K023737

(Optional Format 3-10-98)